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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ATTORNEY DOCKET NO. 079579-0133

Applicant: Gonzalo SERAFICA et al.

Title: MICROBIAL CELLULOSE WOUND DRESSING FOR TREATING
CHRONIC WOUNDS

Appl. No.: 10/732,802

Filing Date: 12/11/2003

Examiner: Unassigned

Art Unit: 1617

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants are presenting a Declaration under Rule 132 with two exhibits, A and B, in order to explain the context of these documents. The two exhibits correspond to documents C5 (which is declaration Exhibit A) and C6 (which is declaration Exhibit B) of the attached form SB-08.

References C3, C4, and C6. None of these references discloses the percent cellulose of the wound dressing described.

Reference C5. Applicants do not believe that reference C5 (Exhibit A to the Declaration) meets the legal requirements to constitute a prior art offer for sale, but it is being submitted for the PTO to make this determination. Specifically, Applicants believe it is not an offer for sale because it lacks an essential term, namely the specifications of the product to be sold under the agreement. A case that involved a similar set of facts is *Elan Corp., PLC v. Andrx Pharm., Inc.*, 366 F.3d. 1336 (Fed. Cir. 2004) (copy enclosed for the Examiner's convenience). The issue in *Elan* was whether or not a letter to a potential partner, "the Lederle letter," constituted an offer for sale. *Id.* at 1340. If the Lederle letter constituted an offer for sale, the claims at issue would be invalid. The Federal Circuit did not address whether or not the product was ready for patenting. *Id.* at 1342.

The Federal Circuit determined that the Lederle letter did not constitute an offer for sale based on the following facts:

1. The Lederle letter did not specify the quantity of product to be sold;
2. The Lederle letter did not specify the time of delivery;
3. The Lederle letter did not specify the place of delivery;
4. The Lederle letter did not provide product specifications;
5. The Lederle letter did not provide price quotes for the products; and
6. The Lederle letter was a license rather than an offer for sale of product (relying, in part, on the other facts).

See Elan, 366 F.3d at 1341. The court concluded that "[a]n offer to enter into a license under a patent for future sale of the invention covered by the patent when and if it has been developed, which is what the Lederle letter was, is not an offer to sell the patented invention that constituted an on-sale bar", even though it included pricing information and reference to a specific product. *Id.* (emphasis added). It rested this holding on the Restatement (Second) of Contracts, § 33(3) (1981), which states that "[t]he fact that one or more terms of a proposed bargain are left open or uncertain may show that a manifestation of intention is not intended to be understood as an offer" (emphasis supplied).

Reference C5 (Exhibit A to the declaration), the agreement between Xylos and the third party ("Agreement"), should not be considered an offer for sale even though it does contain some details not present in the Lederle letter. Specifically, the Agreement has provisions dealing with quantity of product to be sold (Section 7), timing of delivery (Section 9), place of delivery (Section 10), and pricing (Section 11). However, the product specifications are conspicuously absent from the Agreement. Indeed, the Agreement states that the product specifications are to be developed between the parties and formalized in a later technical agreement (Section 2). Thus, as in *Elan*, an essential term of the agreement was left open to later discussions. In addition, "an offer to license a patent claiming an invention after future research and development had occurred, without more, is not an offer to sell the invention." *Id.* at 1341; *In re Kollar*, 286 F.3d 1326 (Fed. Cir. 2002).

In both *Elan* and the present case, (1) the alleged offeror possessed patent rights in the product; (2) the offeror was attempting to seek a partner for marketing product; (3) the payment was to be based, at least in part, on the sale of the product to the marketing partner.

The Federal Circuit has held that license does not constitute an offer for sale. *Id.* at 1341. In a more specific case, conveying "the exclusive right to market the invention" was not "a sale or an offer to sell devices themselves." *Id.* (quoting *Mas-Hamilton Group v. LaGard, Inc.*, 156 F.3d 1206, 1217 (Fed. Cir. 1998)). The Agreement itself states that the third party receives the "sole and exclusive right to market, sell, [and] distribute" the products (Section 4(a)(1)).

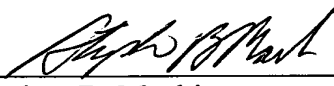
Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

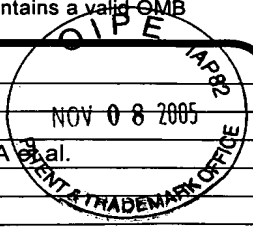
November 2, 2005
Date

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5569
Facsimile: (202) 672-5399


Stephen B. Maebius
Attorney for Applicant
Registration No. 35,264

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
		Application Number		10/732,802	
		Filing Date		12/11/2003	
		First Named Inventor		Gonzalo SERAFICA et al.	
		Group Art Unit		1617	
		Examiner Name		Unassigned	
		Attorney Docket Number		079579-0133	
Sheet	1	of	1		



U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	C1	3,872,862		HUME	03/1975	
	C2	6,320,093		AUGUSTINE et al.	11/2001	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	C3	BROWN-ETRIS et al., "Evaluation of a Biosynthetic Material: A New Wound Dressing Concept," Abstract, 1 Sheet, presented as a poster around April 1998	
	C4	"Some of These Companies Forecast Revenues of More Than \$25 Million," May/June 1999, 1 Sheet.	
	C5	Redacted agreement, Exhibit A to Rule 132 Declaration of Russell Hoon	
	C6	June 22, 1998 510(k) approval no. K974251 for X-Cell Wound Dressing (printed out from FDA web site)	

Examiner Signature	Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.